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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,159	01/18/2005	Jenny Nyberg	09857/0202181-US0	7593

7278 7590 03/19/2007

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,159	NYBERG ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed 10 December 2004 has been entered. Claims 1 – 65 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 – 13 and 22 – 30, drawn to methods of administering compounds identical or similar effects as SEQ ID NO:2 or 4, to the extent that the claims encompass administration of proteins.

Group 2, claim(s) 1 – 8, 11, 22 – 25, and 28, drawn to methods of administering compounds identical or similar effects as SEQ ID NO:2 or 4, to the extent that the claims encompass administration of products of undefined structure.

Group 3, claim(s) 14 – 16, 31 – 33, 40, 52 – 60, drawn to compounds of undefined structure with identical or similar effects as SEQ ID NO:2 or 4.

Group 4, claim(s) 53 – 65, drawn to compounds that are related by sequence identity to SEQ ID NO:2.

Group 5, claim(s) 17 and 20 – 21, drawn to methods comprising administering an antagonist of GIP of undefined structure.

Group 6, claim(s) 18, and 46 – 47, drawn to methods comprising administering an antibody.

Group 7, claim(s) 19 and 48 – 49, drawn to methods comprising administering a GIP receptor antagonist.

Group 8, claim(s) 34 – 35, drawn to methods of administering compounds of undefined structure.

Group 9, claim(s) 36 and 39, drawn to method comprising administering to a subject a pharmaceutical composition comprising a GIP antagonist of undefined structure.

Group 10, claim(s) 37 and 50, drawn to methods of administering an antibody to GIP.

Group 11, claim(s) 38 and 51, drawn to methods of administering an antagonist of a GIP receptor of undefined structure.

Group 12, claim(s) 41, drawn to a method comprising providing a compound for a manufacture of a pharmaceutical composition.

Group 13, claim(s) 42 – 45, drawn to methods of determining an abnormal GIP level.

3. The inventions listed as Groups 1 – 13 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the first stated technical feature, a method of administering a pharmaceutical composition comprising a compound that has at least 50% of the activity of SEQ ID NO:2 to a subject, is not a contribution over the prior art. O'Harte et al. (1999. Diabetes 48:758-765) teach methods of administering both human GIP and a variant thereof. See for example O'Harte p. 761 second column, which teaches administration of these two compounds to Wistar rats. Note that the GIP used was human (see Materials, p. 759) and the specification discloses that SEQ ID NO:2 is human GIP (see specification, p. 8 line 20 – 22). As the prior art teaches both the protein recited in claim 1 and the method of administering it, the reference fairly teaches every limitation of claim 1. Note the claim is not limited to administration to humans and encompasses prophylactic administration, i.e. administration to subjects without a disease or a condition. Thus as the first claimed technical feature is not a special technical feature as defined by PCT Rule 13, unity of invention is lacking.

Furthermore the different groups listed above do not share the same or a corresponding technical feature. Group 1 is drawn to administration of proteins, groups 2 – 3, and 5 – 11 are drawn to different products and methods of using them. Groups 12 – 13 are drawn to different methods which do not require administration of the proteins recited in the methods of Group 1. Group 4 is drawn to proteins, i.e. the same technical feature recited in Group 1, but restriction into separate groups is proper as unity of invention is lacking since the first claimed feature is not a contribution over the prior art.

Since the first technical feature is not a special technical feature as defined by PCT Rule 13, and the remaining groups are drawn to different technical features which are not required for the practice of the methods of Group 1, unity of invention is lacking. Note that PCT Rule 13 does not allow for multiple products or methods within a single application.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker, Ph.D.
March 12, 2007

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER